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Via E-mail

October 14, 2014

Richard Albright, ECL Director
United States Environmental Protection Agency, Region 10
Office of Environmental Cleanup, Mail Code ECL-117
1200 Sixth Avenue, Suite 900
Seattle, Washington 98101-3140

Re: Reply in Support of Request for Dispute Resolution of EPA's Notice of Decisions on Background Regarding Section 7 of the Remedial Investigation (Lower Willamette River, Portland Harbor Superfund Site, USEPA Docket No: CERCLA-10-2001-0240)

Dear Mr. Albright:

The Lower Willamette Group ("LWG") provides this letter in reply to EPA's October 3, 2014 Response to LWG August 26, 2014 Request for Dispute Resolution (the "Response"), concerning the manner in which background concentrations of indicator contaminants are assessed in Section 7 of the revised Draft Remedial Investigation Report (the "RI") for the Portland Harbor Superfund Site (the "Site"). The resolution of this dispute will have significant implications for the ultimate selection of achievable cleanup goals for the Site. The LWG appreciates your willingness to consider its submissions.

I. Introduction

The LWG's technical position in this dispute can be summarized in one simple quote from EPA guidance:

"A data point should not be eliminated from the background data set simply because it is the highest value that was observed." (USEPA 2002a).

The LWG's method of calculating background concentrations—which is based on the inclusion of large, but analytically valid, data points—is the method that should be employed in the RI. It is more accurate and more technically defensible than the method advanced by EPA, and will yield a result that is more relevant to, and reflective of, the Site. Critically, it will also lead to the eventual development of achievable cleanup goals for Portland Harbor.

In contrast, EPA's proposed methodology—which relies on the erroneous assumption that all environmental data should be normally distributed and the consequent elimination of so-called "outliers" that do not comport with that erroneous assumption—fails to account for the specific physical, chemical, and biological conditions of the Lower Willamette River. As such, EPA's proposed methodology violates many of the fundamental aspects of the very guidance that EPA cites in its Response.

This reply letter focuses on two principle technical issues: (1) errors in EPA's statistical methodologies; and (2) the salience of other lines of evidence related to the background area conditions and concentrations. It also addresses EPA's erroneous statement regarding the applicable standard of review and makes clear that the arbitrary and capricious standard is inapplicable to the current dispute.

II. Disputed Issues

A. EPA erred in its application of statistical methodologies.

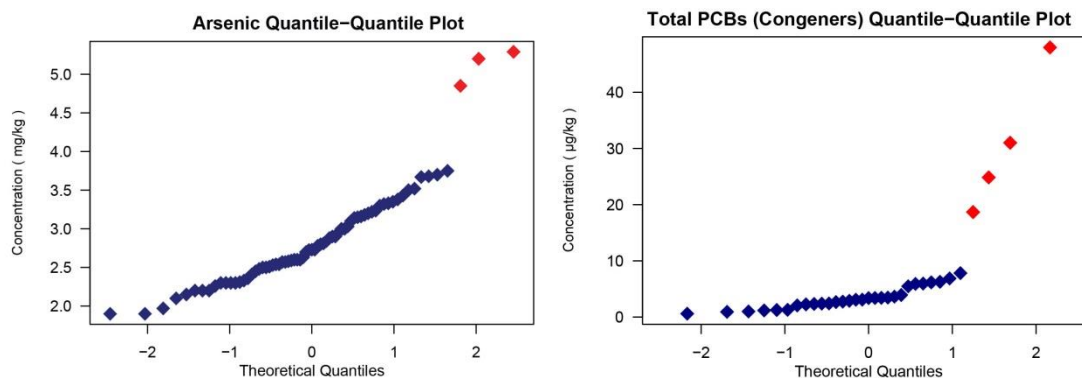
EPA has removed background data that do not conform to its assumption that such data must follow a normal distribution, despite the fact that there is no scientific evidence suggesting that the removed background data are not valid. This is scientifically indefensible and contrary to applicable EPA guidance.

The text on page 7 of USEPA (2002b) supports the conclusion that scientifically valid observations cannot be arbitrarily removed from the background data: “The reasons for this approach include cost-effectiveness, technical practicability, and *the potential for recontamination of remediated areas by surrounding areas with elevated background concentrations* [emphasis added].”

On pages 4 and 15 of its Response, EPA is arguing that:

1. Datasets with “inflated” observations (regardless of whether these observations are valid) will yield BTVs (background threshold values) that are, in EPA’s opinion, “distorted” (page 15);
2. Background data used to compute BTVs must therefore follow a normal (Gaussian) distribution in order to ensure BTVs are not too large (page 16); and
3. It is therefore justifiable to remove any data that do not conform to the assumption that background data must follow a normal distribution, even if there is no scientific evidence that the data removed are not valid (page 21).

It is not scientifically valid to discard data simply because including that data would produce unwanted results. Correctly dealing with data that do not agree with an assumed statistical model transcends the environmental medium or regulatory program that is under discussion, and is a discussion in scientific literature. The LWG and EPA fundamentally disagree about the assumed distribution for background data. In natural alluvial systems, like the Willamette River, it is not reasonable for EPA to assume that the sediment characteristics and associated chemical data are normally distributed. This is acknowledged in relevant EPA guidance (USEPA 2013a). The quantile-quantile (Q-Q) plots below show the arsenic (left) and PCB congener (right) background data sets. On a Q-Q plot, normally distributed data show a linear pattern. Right-skewed (e.g., gamma and lognormally distributed) data plot in an upward-curving pattern. ProUCL and EPA identify the red diamonds as outliers under the assumption that the data is normally distributed. In this fluvial system, both arsenic (a naturally occurring metal) and PCBs (an anthropogenic background contaminant) show an upward curving pattern (*i.e.*, a lognormal-type distribution), which reflects a right skewed distribution resulting from the sediment texture heterogeneity discussed in more detail below.



EPA’s assumption that background area data must follow a normal distribution for all contaminants of concern (COCs) is in direct contradiction to natural alluvial processes and is further supported by decades of scientific research, as well as the EPA guidance documents that EPA cites as relevant:

“The following discussion outlines some basic statistical concepts in the context of *background data evaluation*. . . . *Some environmental sample sets are normally distributed. However, the majority of environmental contamination data sets are not normally distributed*. . . . If the data are not normally distributed, log or other types of transformations should be conducted to approximate normality prior to using the data sets in statistical comparisons, such as t-tests or analysis of variance procedures (ANOVA).” USEPA (1995), at 19–20 (emphasis added).

“*If data are not normally distributed, which is often the case for environmental data* [see Ott (1990) and McBean and Rovers (1992) for discussions of why environmental measurements follow a lognormal pattern], an alternative approach like the one discussed in EPA (1989e) or EPA (1995) could be used if data are lognormally distributed.” USEPA (1995) at 23 (emphasis added).

“*. . . it is unusual to encounter environmental data sets that are normally distributed* Usually the logarithms of the data have been applied to the raw data. The test for normality is then applied to the transformed data sets.” USEPA (2002a) at 4-2 (emphasis added).

“Many environmental data sets can be modeled by a gamma as well as a lognormal distribution.” USEPA (2013a) at 1.

As all of these guidance documents illustrate, environmental data are often skewed.

B. EPA failed to consider other lines of evidence related to background area conditions and contaminant concentrations.

EPA’s arguments to remove outliers from the background area data set are based on two false premises:

1. The elevated concentrations identified as outliers do not fall within the dominant population (*i.e.*, are elevated and therefore not representative of background area conditions); and
2. It is acceptable to remove presumed outliers from the background data set without conducting a weight-of-evidence or other independent evaluation to assess whether they should, in fact, be removed.

Using Total PCBs (based on congeners) as an example, the following subsections address these two key elements that are critical to the assessment and determination of site-specific background conditions and the establishment of background area concentrations of contaminants.

1. PCB congener concentrations in the background area data set are indicative of the dominant population (*i.e.*, anthropogenic background).

EPA guidance is clear that background conditions are site-specific (e.g., “Site-specific BTVs are used in site versus background evaluation studies” and “to compare onsite constituent concentrations with site-specific background level constituent concentrations.” (EPA 2013a). The Lower Willamette River exhibits unique physical, chemical, and biological conditions relative to other sediment Superfund sites, and therefore warrants a site-specific analysis. Specific to EPA Region 10, the following are a few key differences between the watersheds of the Lower Willamette River and Duwamish/Green River (per their respective RI studies):

- Size - Duwamish/Green: about 440 square miles; Willamette: about 11,400 square miles.
- Population - Duwamish/Green: ~400,000; Willamette: ~2,700,000 (~70% of Oregonians, including cities of Springfield, Eugene, Corvallis, Albany, Salem, McMinnville, Newburg, Wilsonville, Oregon City, Milwaukie, and Portland).

- Flows - Duwamish/Green: averages 1,500–3,000 cubic feet per second (cfs), peaks around 11,000 cfs; Willamette: averages 20,000 to 30,000 cfs, peaks over 400,000 cfs.

Therefore, the potential anthropogenic contribution of contaminants to the Lower Willamette River from its corresponding watershed is much greater than the Duwamish River. Even if large values observed in the background data were found to be associated with previously unknown contamination sources, in the absence of any action to remediate those particular sources, the contaminants migrate into the Site (USEPA, 2002b, p.7).

EPA states: “This [background] area was chosen because it is considered broadly representative of the upstream sediment concentrations resulting from point and non-point sources within the broader watershed and unaffected by either localized point sources or Portland Harbor itself.” Response at 6. Understanding the size of the Willamette River watershed and the inputs from its large, highly developed basin, it is not unreasonable to expect a wide range of concentrations of persistent bioaccumulative contaminants (e.g., PCBs) in the background area. Key questions are:

- At what point are concentrations considered too high to represent the anthropogenic background values?
- Are the elevated data geographically clustered and therefore may represent a localized source, or are they scattered and therefore represent watershed inputs?

In the absence of documented information about potential background area contaminant sources, EPA wrote in a July 24, 2008 response letter to the LWG’s July 3, 2008 memo on Background Data Processing and Outlier Identification that:

“Potential outliers should be evaluated on a geographic basis. Potential outliers that are clustered together are indicative of local sources of contamination and thus are not reflective of background conditions. Clustered outliers should be eliminated from the background data set. **Potential outliers that are distributed geographically may be retained.**” (Emphasis added.)

The four total PCB congeners samples EPA discarded as outliers are widespread (*i.e.*, not associated with a known or suspected current or former source). *See* Exhibit A. Also, the physical characteristics of these samples best represent the grain size and organic carbon (OC) content of the majority of Study Area sediment samples. PCB concentrations are generally lower in samples with large grain sizes and low OC than samples with smaller grain sizes and higher OC content. The four total PCB congener samples discarded by EPA actually exhibit these correlation patterns and the respective concentrations are within the range expected to exist within the “broader, heterogeneous watershed.”

Moreover, at page 14 of its Response, EPA states:

The background data set was deemed “representative of the urban and suburban upland conditions of the Willamette River...uninfluenced by releases from the Portland Harbor site.” With this in mind, EPA’s analysis of the background data assumed those data provided by the LWG were sufficient to estimate sediment concentrations while also representing inputs from the broader watershed. The watershed has sources that cannot otherwise be reliably controlled, but EPA did not examine whether specific samples were “more representative” of the study area than others. In fact, the grain size and organic carbon content of sediments within the study area represent a broad range of values. The key factor in identifying potential outliers was not absolute concentration, or whether the sediment characteristics were “more like the study area,” or “most likely to be transported.” Rather, consistent with the repeated recommendations in EPA guidance, EPA’s analysis focused on the degree of influence the inclusion of suspected outlier values exerted on the subsequent calculation of BTV and mean values.”

This point actually supports the LWG's argument for *not* excluding the alleged PCB congener outliers. The four PCB congeners samples discarded by EPA are in fact representative of sediments uninfluenced by releases from Portland Harbor or other specific sources, and accurately represent inputs from the broader watershed. As such, they *should* exert influence on the subsequent calculation of BTV and mean values.

EPA also states at page 23 of its Response:

“As EPA has stated before, the background data set is meant to represent the loading from the broader watershed, not from the upriver reach of the river. However, the LWG has conducted no analysis of the potential sediment and contaminant mass available in this reach of the river for scour and re-deposition, as all mass-loading analyses in the 2011 draft RI and 2013 draft FS included data collected down to RM 11.”

Per EPA guidance, the RI is to assess and present an analysis of the *current* physical, chemical, and biological information (EPA 1988). This information can then be utilized in various FS analyses to assess potential *future* conditions (e.g., post-remedy recontamination). The LWG agrees with EPA's following statement, found at page 24 of its Response:

“EPA acknowledges that there are sources in the upriver reach and the downtown corridor that will affect the ability of the Study Area to equilibrate to the background concentrations. However, this is not a justified reason for concluding that the background concentrations or the long-term goals should be set to the current loadings.”

The RI analysis of background concentrations is strictly an objective exercise to explain *current* conditions. FS analyses will assess both the *current* understanding of contaminant loading, and *future* projections of potential loading. As described below, it is clear that the four PCB congener samples discarded by EPA as outliers are in fact representative of the dominant population for the background area and need to be included in the FS analyses.

EPA states that it “appropriately excluded outliers based on a scientific analysis of the background data set consistent with appropriate EPA guidance documents.” Response at 13–14. EPA's Response leans heavily on statements in ProUCL's Technical Guide (USEPA 2013b, referred to as the “Guide”) regarding generating statistics from the “main dominant population” only. EPA quotes page 17 of the Guide on page 4 of its Response:

[i]n a background data set, in addition to reporting and/or laboratory errors, statistical outliers may also be present. **A few elevated statistical outliers present in a background data set may actually represent potentially contaminated locations belonging to impacted site areas and/or possibly from other polluted site(s);** concentrations represented by those elevated outliers may not be coming from the main dominant background population under evaluation...and further that **“the occurrence of elevated outliers is common when background samples are collected from various onsite areas.** The proper disposition of outliers, to include or not include them in statistical computations, should be decided by the project team. The project team may want to compute decision statistics with and without the outliers to evaluate the influence of outliers on the decision making statistics.”

The **bolded statements** quoted above reveal the primary concern of the guidance is identifying and removing outliers from a background data set which may represent contamination from either “various onsite areas” or “other polluted site(s).” This is a valid concern when a background data set is being generated by sampling subareas within a site that are presumed to be uncontaminated, particularly when water and sediment transport patterns are variable or not well defined. But it is not a valid concern when evaluating background areas that EPA acknowledges are “representative of the urban and suburban upland conditions of the Willamette River . . . uninfluenced by releases from the Portland Harbor site” and that the

data are “sufficient to estimate sediment concentrations while also representing inputs from the broader watershed.”

The LWG has consistently asserted that site-specific information, such as the geographic distribution, should be used to support the outlier disposition evaluations. EPA’s own guidance also supports this type of evaluation:

“To assess the influence of outliers on the various statistics (e.g., upper limits) of interest, it is suggested to compute all relevant statistics using data sets with outliers and without outliers, and compare the results.... This in turn will help the project team to make informative decisions about the disposition of outliers. That is, the project team and experts familiar with the site should decide which of the computed statistics (with outliers or without outliers) represent better and more accurate estimate(s) of the population parameters (e.g., mean, EPC, BTV) under consideration. **Since the treatment and handling of outliers is a controversial and subjective topic, it is suggested that the outliers be treated on a site-specific basis using all existing knowledge about the site; and regional and site-specific background areas.**” USEPA (2013b) at 85 (emphasis added).

“A data point should not be eliminated from the background data set simply because it is the highest value that was observed.” USEPA (2002a).

2. EPA must conduct a weight-of-evidence approach or an independent evaluation before removing outliers from the background data set.

The LWG disagrees with EPA’s decision to explicitly exclude the supportive lines of evidence in determining background concentrations given the clear EPA guidance on this issue (USEPA 2009b and 2013a). Consideration of supportive lines of evidence results in more accurate background statistics, which will ultimately lead to more effective remedial alternatives/decisions.

a. EPA disregards relevant guidance documents.

EPA argues that the LWG’s support for a weight of evidence approach is hinged on one reference document (EPA 2009b), and EPA deems this document “inappropriate” for this use at the site. The passages in USEPA (2009b) pertaining to the handling of outliers regardless of media, and are directly applicable to the issues in dispute, including page 1-4:

“There are also comparable situations involving other environmental media to which the Unified Guidance statistical methods might be applied . . . [t]he guidance describes diagnostic techniques for checking the assumptions underlying many statistical procedures. Testing of normality is ubiquitous in environmental statistical analysis.”

The LWG’s Request for Dispute Resolution also referenced numerous other EPA guidance documents supporting the multiple lines of evidence approach, including:

- Page 13: USEPA’s 2013 ProUCL Technical Guide;
- Page 15: USEPA’s 2002 Guidance for Comparing Background and Chemical Concentrations in Soil for CERCLA Sites;
- Page 15: USEPA’s 2002 Role of Background in the CERCLA Cleanup Program; and
- Page 16: USEPA 2005 Contaminated Sediment Remediation Guidance for Hazardous Waste Sites.

EPA also disregards the use of *Data Quality Assessment: A Reviewer’s Guide*. (USEPA 2006a). As pointed out in the LWG’s Request for Dispute Resolution, page 51 of USEPA (2006a) states: “If scientific reasoning does not explain the outlier, it should not be discarded from the data set.” EPA does not address the use of this guidance document in its Response.

At page 13 of its Response, EPA also asserts, contrary to its own guidance, that:

It is not necessary for EPA to conduct a weight-of-evidence approach or to conduct an independent evaluation to remove outliers from the background data set. In the context of determining the natural and anthropogenic background from the broader Willamette watershed, the definition of an outlier is simply the classical one of not being representative of the majority of the data.

The EPA project team is subjectively deciding what is and is not representative. Further, the narrow definition of an outlier presented above is clearly contrary to the position expressed by the EPA project team in 2008.

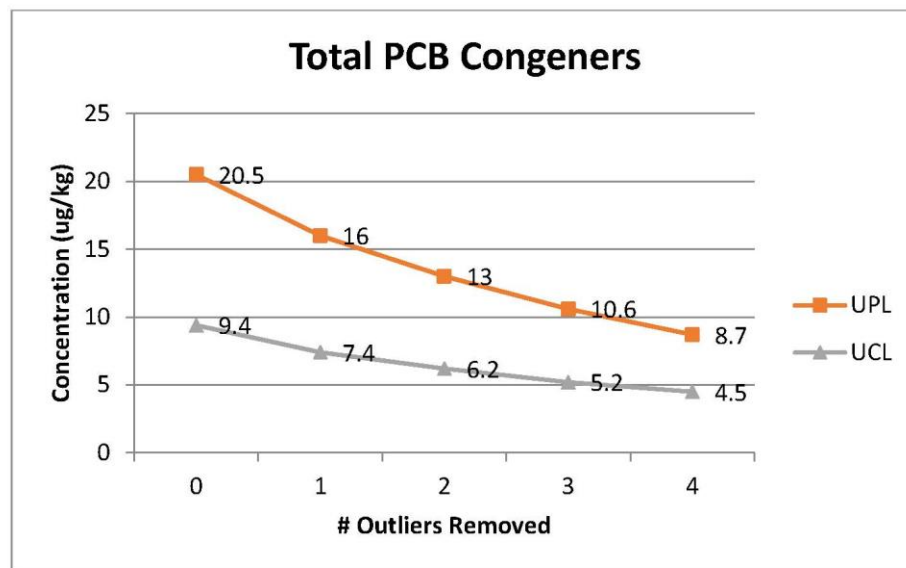
EPA's approach to the treatment of outliers is not based on sound technical or scientific ground and does not adequately address this "controversial and subjective" issue. More importantly, it does not provide the most accurate background statistic estimates for use in the FS.

b. Multiple lines of evidence support the inclusion of the data at issue.

Exhibit A (Upstream Congener Map) shows the mapped distribution of the PCB congener data. Two concentration-by-river mile panels are shown inset on this map with the statistical outliers per ProUCL identified in red; the left panel is the PCB data in dry weight units ($\mu\text{g/kg}$), the right panel is the same data set normalized for organic carbon ($\mu\text{g/kg-C}$). The data table inset on the lower right provides the PCB congener ($\mu\text{g/kg}$) and percent total organic carbon values for each sample. As for geographic distribution, the four alleged outliers occur at river miles 16, 24.4, 26.9, and 28.3. These four elevated values are dispersed throughout the background reach and are juxtaposed to samples with lower PCB concentrations. This pattern provides no indication of a potential specific source.

As for sample physical characteristics, it is well established that hydrophobic organic compounds are associated with organic carbon in sediment samples. The percent total organic carbon (TOC) for each sample is included in Exhibit A (data table). The mean TOC of the four "outliers" is 1.68%, while the mean TOC percentage of the remainder of the samples is 0.97%. Note that 1.68% TOC approaches the mean TOC for all surface sediment samples from the Study Area of 1.79%. The right panel inset on Exhibit A is a plot of this PCB congener data set normalized for organic carbon on a sample-by-sample basis ($\mu\text{g/kg-C}$). When the data are carbon normalized, three of the four samples fall well within the dominant population and the fourth is within the tail of the distribution of the dominant population.

Together, these two primary lines of evidence point to a heterogeneous upriver physical setting where small pockets of higher organic content sediments are deposited in lower energy or sheltered areas, likely temporarily on both seasonal and annual time scales. Note in the Exhibit A map that three of the four statistical outliers are downstream of land forms (RM 28.3 and RM 24.4) or manmade overwater structures (RM 16); such features likely create lower-energy subareas where finer grained material accumulates. As recognized by EPA in their acceptance of organic carbon correction concentrations, higher concentrations of hydrophobic organic compounds are associated with higher TOC levels.



As a secondary line of evidence, we compared the measured concentrations of PCB congeners on suspended sediments collected at the downstream end of the background reach with the background statistics calculated with all data and EPA’s “outliers” removed. Figure 2 from EPA’s Response (above) illustrates the background statistics with sequential impact of removing the Total PCB congener “outliers” on the calculated upper threshold (UPL) and central tendency (UCL) statistics.

As part of the RI, PCB congener concentrations were measured on suspended sediment collected during four separate surface water sampling events at RM 16, at the downstream end of the background reach. Samples were collected in 2006 (Jan., Sept., and Nov.) and 2007 (Jan.) and captured high, low, and storm-water influenced flow regimes. Although the sample set is limited, it is a direct measure of the concentrations of PCB congeners on suspended particles moving downstream from the background reach and before they enter the downtown reach or Portland Harbor. The CSM for the site indicates that, depending on the hydrographic conditions, much of this upriver sediment load will be deposited in the Study Area as the river enters Portland Harbor and the channel widens. Basic summary statistics for this data set are provided below.

Suspended Sediment at RM 16	N	Min	Mean	Median	95 th Percentile	Max
Total PCB Congeners (µg/kg)	7	1.6	9.0	9.2	21.5	24.6

Comparing the values in Figure 2 with these summary statistics, the two central tendency metrics (mean and median) are equal to about 9 µg/kg, which approximates the all data background UCL of 9.4 µg/kg. The 95th percentile value is 21.5 which approximates the all data background UPL of 20.5 µg/kg. Both of these values are notably higher than the 4.5 UCL and 8.7 UPL, respectively, calculated with all outliers removed from the background data set.

The geographic distribution and sample physical characteristics indicate that the “outliers” are part of the anthropogenic background population, and an independent measure of suspended sediment quality moving downstream from the background reach most closely approximates background PCB statistics calculated with all data points included.

C. The arbitrary and capricious standard of review is not applicable to this dispute.

In its Response, EPA asserts that you should employ the arbitrary and capricious standard of review when evaluating the issues put into dispute by the LWG, relying on Section 113 of CERCLA. *See* Response at 2 (citing 42 U.S.C. § 9613(j)(1)–(2)). This is incorrect.

The standard of review specified by CERCLA Section 113—captioned “Civil proceedings”—relates solely to judicial proceedings of reviewable agency actions. *See* 42 U.S.C. § 9613(j)(2) (“In considering objections raised in any **judicial action** under this chapter, the **court** shall uphold the President’s decision in selecting the response action unless the objecting party can demonstrate, on the administrative record, that the decision was arbitrary and capricious or otherwise not in accordance with law.” (emphasis added)). It has no role in an administrative dispute process, the purpose of which is to foster the resolution of technical (and other) disagreements before final agency decisions are made and before judicial review is available. In fact, the AOC’s Dispute Resolution provision says nothing about the standard of review you are to employ. *See* AOC § XVIII (simply providing that the LWG must “define the dispute” and “state the basis of [its] objection(s),” that the LWG, after attempting to resolve the dispute with EPA staff, “may request a determination by EPA’s Environmental Cleanup Office (ECL) Director,” and that the ECL Director may then issue a determination that will constitute the “EPA’s final decision” for purposes of the AOC).

Contrary to EPA’s suggestions, your role as arbiter of this dispute is not constrained by a standard of review that could apply in the context of judicial proceedings. Rather, it is to ensure that EPA has appropriately applied its guidance and fundamental statistical concepts in defining the background data set applicable to the Site. While the decision you render in this dispute will constitute the EPA’s “final decision” under the AOC, which may ultimately be subject to the arbitrary and capricious standard of review, that standard of review has no bearing on your review of the disputed issues presented in the LWG’s Request.¹

Finally, the LWG disagrees with several of the references to past agreements and project history set forth in the Response. The LWG has not addressed these issues in this reply letter because they are not directly germane to the subject of this dispute.² The LWG will, however, provide documented corrections to these references under separate cover in order to ensure the accuracy of the administrative record.

III. Conclusion

EPA’s proposed methodology for handling large, but analytically valid, background data results in an artificially constrained background data set that is inconsistent with applicable guidance and technically indefensible. The LWG respectfully requests that you determine that the full background data set with consideration of organic carbon correction be used for purposes of calculating background. The LWG also reiterates its request for oral presentation, so as to aid the decision-making process.

Sincerely,



¹ In its Request, the LWG stated that EPA had “abused its discretion” when it interpreted and applied guidance relevant to this dispute. *See, e.g.*, Request at 2, 8, 9, and 11. What the LWG meant to convey by using that phrase was that the EPA fundamentally erred because its approach was contrary to applicable guidance (in certain instances) and to accepted scientific protocols (in other instances). The LWG did not intend to invoke the “abuse of discretion” standard of judicial review or to suggest that it should somehow apply in resolving this dispute, and regrets that this language led EPA to conclude that we were employing this standard.

² With respect to EPA’s footnote 2, however, the LWG would like to clarify that the “original direction” referenced in that footnote appears to be EPA comments provided during discussion of RI Section 7 in 2013. According to the September 24, 2013 RI Process Agreement, EPA comments do not become directive until EPA’s letter transmitting final changes to all sections of the RI Report. The LWG has not yet received such a letter. The LWG has worked in good faith to complete the RI consistent with the RI Process Agreement. While the LWG has not yet provided Section 7 tables and figures to EPA, that is simply because they are not yet due.

The Lower Willamette Group

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